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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/823,418

03/29/2001

Thomas Innerarity

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06/02/2004

MORRISON & FOERSTER LLP

755 PAGE MILL RD

PALO ALTO, CA 94304-1018

EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/823,418

Applicant(s)

INNERARITY ET AL.

Examiner

Anish Gupta

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restriction

The outstanding restriction/election is vacated. An office action on the merits follows below.

Amendments

The amendment filed 3-29-01 has been entered. Claims 1-22 and 24-28 were canceled and claim 23 was amended. Claim 23 is pending in this application.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claim 23 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a polynucleotide Apo-B100 protein comprising a proteoglycan receptor mutation in Site B. It should be noted that numerous organisms have differing amino acids in the Site B relative to the human apo-B100. For example, Law et al. teach Hamster apo sequence that has the sequence SRLTRKRGLK in position 3359-3367 (see page 1114 of Law et al.). This sequence meets the claimed limitation of claims 14 since the 3359 Serine residue is different than the 3359 Threonine residue of human apo-B100. The reference also discloses polynucleotide sequence that encodes the Apo-B100 protein (see pages 1112-1115). Since the polynucleotides that encode the Apo-B100 are found in the plasma of numerous animals, including hamster, and the claim does not state isolated or purified, the claimed product would qualify as a product of nature and hence non-statutory subject matter.

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An amendment to the claim to state an "isolated and purified polynucleotide" will be sufficient to overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Law et al. (J. Lipid Research).

The claims are drawn to a polynucleotide that encodes Apo-B100 protein comprising a proteoglycan receptor mutation in Site B. Site B is defined as position *about* 3359 to *about* 3369. The claims also state that the site B is flanked on at least one side by contiguous sequence of at least 10 amino acids which is directly adjacent to site B in the wild type human apo-B100 sequence. The rejection assumes that apo-B100 is human apo-B100.

The reference discloses numerous apo-B100 sequence that have sequences that have mutations in site B when compared to the human apo-B100 (see page 1114). The reference also discloses all of the nucleic acid sequences that encode the protein for the various species of animals (see page 1112-1114).

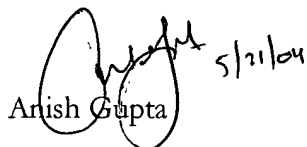
For example, the reference discloses a rabbit apo-b sequence, which has the sequence SSLTRKRGLKLA in position 3358-3359 (see page 1114). The human apo-b sequence in this range is TRLTRKRGLKL. Note that rabbit apo-b contains two different amino acids in positions 3358 and 3359. The instant specification a mutant of apo-B100 involve substitutions of four amino acid positions, 3363, 3362, 3364 and 3359 (see page 17). Since the reference discloses a mutation in

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position 3359, the reference meets all of the limitations mutation to site B. The reference also discloses rat, hamster, mouse, chicken and pig which would qualify as apo-B100 mutation as explained above and meet the limitations of the claim (see page 1114). The Pig sequence disclosed is SLMRKRGGL in positions 3359-3367 (see page 1114). Note that 3359 and 3361 differ from the native human apo-B100 and therefore would qualify as mutations in these position with respect to human apo-B100. The reference also states that region B of the apo-B100 is from 3359-3367 (see page 1109 and 1110). Therefore, the reference anticipates claim 23 since the reference discloses polynucleotide sequences that encode Apo-B100 proteins that contains mutations in site B.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

 5/21/04
Anish Gupta

Patent examiner.